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U.S.A., Inc.

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

_____	x	
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TARO PHARMACEUTICALS NORTH	:	Honorable Jose L. Linares, U.S.D.J.
AMERICA, INC. and TARO	:	
PHARMACEUTICALS U.S.A., INC.,	:	Civil Action No. 09 CV 3569 (JLL)(CCC)
	:	
	:	
Plaintiffs,	:	
	:	<b>PLAINTIFFS' ANSWER TO SECOND</b>
v.	:	<b>AMENDED COUNTERCLAIMS OF</b>
	:	<b>DEFENDANT, SYNERX PHARMA, LLC</b>
SYNERX PHARMA, LLC; KARALEX	:	
PHARMA, LLC; and DPT LABORATORIES,	:	
LTD.,	:	
	:	
Defendants.	:	<b>Document Filed Electronically</b>
	:	
_____	x	

Plaintiffs Taro Pharmaceuticals North America, Inc., and Taro Pharmaceuticals U.S.A., Inc. (collectively "Plaintiffs" or "Taro") by way of Answer to the following numbered paragraphs of Defendant, Synerx Pharma, LLC's Second Amended Counterclaims, states:

**THE PARTIES**

29. Counter-plaintiff Synerx Pharma LLC (“Synerx”) is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 100 North State Street, Newtown, Pennsylvania.

**ANSWER**

**29. Admitted.**

30. On information and belief based on the allegations of the Complaint, Taro Pharmaceuticals North America is a corporation organized and existing under the laws of the Cayman Islands, having its principal place of business at 103 South Church Street, Grand Cayman, Cayman Islands.

**ANSWER**

**30. Admitted.**

31. On information and belief based on the allegations of the Complaint, Taro Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of New York, having a place of business at 3 Skyline Drive, Hawthorne, New York. Taro Pharmaceuticals North America, Inc, and Taro Pharmaceuticals USA Inc. are referenced herein collectively and individually as “Taro.”

**ANSWER**

**31. Admitted.**

**THE CONTROVERSY**

32. On information and belief based on the allegations of the Complaint, Taro is the owner of U.S. Patent No. 7,560,445 (the “445 patent”). The ‘445 patent is directed to the purity of malathion.

**ANSWER**

**32. Plaintiffs admit that Taro North America owns the '445 patent and aver that the '445 patent speaks for itself.**

33. On information and belief based on the allegation of the Complaint, Taro holds an approved New Drug Application (NDA) for 0.5% malathion topical lotion (hereinafter "the NDA product.")

**ANSWER**

**33. Admitted.**

34. Synerx is the owner of Abbreviated New Drug Application No. 078743, which is directed to a generic version of the NDA product. Synerx received FDA approval on March 6, 2009 for this generic malathion product.

**ANSWER**

**34. Admitted.**

35. Immediately upon receiving notice of Synerx's FDA approval, and even before the '445 patent issued, Taro threatened Synerx with suit. In a letter dated March 12, 2009, Taro's counsel warned Synerx that "a sale of a generic malathion lotion would violate Taro's rights."

**ANSWER**

**35. Plaintiffs deny that Taro threatened Synerx with suit before the '445 patent issued or upon receiving notice of Synerx's FDA approval. Plaintiffs admit a letter dated March 12, 2009, states that "a sale of a generic malathion lotion would violate Taro's rights." Plaintiffs deny the remaining allegations set forth in paragraph 35 of the Second Amended Counterclaim.**

36. As of March 12, 2009, on information and belief, Taro had no test data or other information showing the impurity profile of the malathion in Synerx's generic malathion product.

**ANSWER**

**36. Denied.**

37. Despite Taro's threat, Synerx went forward with commercialization of its generic malathion product, and sold it into the marketplace.

**ANSWER**

**37. Plaintiffs deny that Taro threatened Synerx. Plaintiffs admit that Synerx sold a malathion product into the marketplace.**

38. On July 14, 2009, the '445 patent issued. Two weeks later, Taro sued Synerx for infringement of the '445 patent.

**ANSWER**

**38. Plaintiffs admit that the '445 patent issued on July 14, 2009. Plaintiffs filed suit against Synerx Pharma, LLC, Karalex Pharma, LLC, and DPT Laboratories, LTD., on July 20, 2009.**

39. Upon information and belief, Taro sued both the manufacturer of Synerx's generic malathion product and the wholesaler of Synerx's generic malathion product, without independent investigation concerning whether any allegedly infringing manufacture or sales had occurred during the term of the '445 patent. Despite representations from both the manufacturer and the wholesaler that no such sales had taken place, Taro continues to maintain its lawsuit.

**ANSWER**

**39. Plaintiffs admit that Taro sued both the manufacturer of Synerx's generic malathion product and the wholesaler of Synerx's generic malathion product. Otherwise, denied.**

40. On information and belief based at least on the suits brought against Synerx's co-defendants, Taro is using the '445 patent in an effort to interfere improperly with Synerx's continued commercialization of a generic malathion product.

**ANSWER**

**40. Denied.**

41. On information and belief, Taro will continue to use the '445 patent to interfere with Synerx's commercialization of its generic malathion product until and unless the claims of that patent are declared invalid or not infringed by Synerx's malathion product.

**ANSWER**

**41. Denied.**

42. Synerx plans to continue having its generic malathion product manufactured and marketed, Synerx is thus in a position of either pursuing behavior that Taro claims is illegal, or abandoning that which Synerx claims a right to do.

**ANSWER**

**42. Plaintiffs are without knowledge or information sufficient to either admit or deny the allegations set forth in paragraph 42 of the Second Amended Counterclaim and therefore deny the same.**

**JURISDICTION AND VENUE**

43. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it arises under the patent laws of the United States.

**ANSWER**

**43. Admitted.**

44. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. § 2201 and 2202 because this is, as described above, a case of actual controversy within the Court's jurisdiction. Synerx is entitled to seek a declaratory judgment that the claims of the '445 patent are either invalid or not infringed.

**ANSWER**

**44. Admitted, except that Plaintiffs expressly deny that the claims of the '445 patent are either invalid or not infringed.**

45. Venue is proper in this District pursuant to 28 U.S.C. §1391.

**ANSWER**

**45. Admitted.**

**THE CLAIMS OF THE PATENT ARE INVALID OR NOT INFRINGED**

46. Upon information and belief, in 1982 the FDA granted final approval to New Drug Application No. 18-613 covering a 0.5% malathion product for treatment of head lice.

**ANSWER**

**46. Admitted.**

47. Taro is the holder of New Drug Application No. 18-613 covering a 0.5% malathion product.

**ANSWER**

**47. Admitted.**

48. More than one year prior to the priority date of the '445 patent, a malathion-containing product called "Ovide® (malathion) Lotion 0.5%" was sold in the United States (hereinafter "the prior art Ovide® Lotion").

**ANSWER**

**48. Plaintiffs admit that a malathion lotion product was sold under the brand name OVIDE more than one year before the priority date of the '445 patent, but deny that any such products are prior art as against any claims of the '445 patent.**

49. Every claim of the '445 patent includes a limitation specifying the level of an impurity called "methyl malathion" ("the methyl malathion limitation").

**ANSWER**

**49. Admitted.**

50. The '445 patent describes two different chemical compounds as "methyl malathion": one compound having phosphorous double bonded to sulfur (*see* col. 5, line 65-col. 6, line 2), and the other compound having the same phosphorous double bonded to oxygen (*see* col. 22, lines 43-46).

**ANSWER**

**50. Plaintiffs admit that methyl malathion is defined at '445 patent col. 5:65-col. 6:2 and mono-methyl malathion is depicted at col. 22:38-59.**

51. On information and belief, one or more batches of the prior art Ovide® lotion contained between 0.1% and 0.2% methyl malathion as defined in col. 5, line 65 - col. 6, line 2

of the '445 patent. These batches contain an amount of methyl malathion that falls outside of the methyl malathion limitation of all of the '445 patent's composition claims.

**ANSWER**

**51. Plaintiffs admit that OVIDE-brand malathion lotion sold before the priority date of the '445 patent contained amounts of methyl malathion that fell outside the methyl malathion limitation of the '445 patent's claims.**

52. On information and belief, the prior art Ovide® lotion contained less than 0.02% methyl malathion as defined in col. 22, lines 43-46 of the '445 patent. These batches contain an amount of methyl malathion that would fall within the methyl malathion limitation of all of the '445 patent's composition claims.

**ANSWER**

**52. Denied.**

53. Multiple articles published more than a year before the priority date of the '445 patent report the preparation of malathion of greater than 99.9% purity.

**ANSWER**

**53. Plaintiffs are without knowledge or information sufficient to either admit or deny the allegations set forth in paragraph 53 of the Second Amended Counterclaim and therefore deny the same.**

54. Malathion of greater than 99.9% purity contains less than 0.1% total impurities and less than 0.1% of any single impurity.

**ANSWER**

**54. Plaintiffs object that Paragraph 54 is a hypothetical tautology, not an allegation of fact.**



55. At the time of the alleged invention of the '445 patent, malathion was known to contain impurities that were more toxic to mammals than malathion itself.

**ANSWER**

**55. Denied.**

56. At the time of the alleged invention of the '445 patent, it was known to a person of ordinary skill in the art that malathion was the pharmaceutically-useful component of the prior art Ovide® lotion.

**ANSWER**

**56. Plaintiffs are without knowledge or information sufficient to either admit or deny the allegations set forth in paragraph 56 of the Second Amended Counterclaim and therefore deny the same.**

57. At the time of the alleged invention of the '445 patent, it would have been obvious to a person of ordinary skill in the art how to prepare malathion with the levels of impurities claimed in the '445 patent.

**ANSWER**

**57. Denied.**

58. At the time of the alleged invention of the '445 patent, it would have been obvious to incorporate malathion with the levels of impurities claimed in the '445 patent into the prior art Ovide® lotion.

**ANSWER**

**58. Denied.**

59. On information and belief, there is no unexpected result, commercial success or other secondary consideration favoring a conclusion of nonobviousness.

**ANSWER**

**59. Denied.**

60. For at least the foregoing reasons, multiple claims of the '445 patent are invalid under 35 U.S.C. §§ 102, 103 and/or 112.

**ANSWER**

**60. Denied.**

61. Multiple claims of the '445 patent, if they were valid, would not be infringed by Synerx's generic malathion product.

**ANSWER**

**61. Plaintiffs aver that the claims of the '445 patent are valid and Synerx's generic malathion product infringes one or more claims of the '445 patent. Plaintiffs are without knowledge or information sufficient to either admit or deny the remaining allegations set forth in paragraph 61 of the Second Amended Counterclaim and therefore deny the same.**

62. No valid claim of the '445 patent would be infringed by Synerx's product.

**ANSWER**

**62. Denied.**

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs deny that Defendants are entitled to any relief sought, and prays that judgment be entered in Plaintiffs' favor against Defendants, and that Plaintiffs be awarded its costs, attorneys' fees, and such other and further relief the Court deems appropriate.

WINSTON & STRAWN LLP  
Attorneys for Plaintiffs  
*Taro Pharmaceuticals North America, Inc.*  
*Taro Pharmaceuticals U.S.A., Inc.*

By: s/ James S. Richter  
James S. Richter

Dated: January 19, 2011

**CERTIFICATION OF SERVICE**

The undersigned attorney certifies that he caused a copy of the foregoing **PLAINTIFFS' ANSWER TO SECOND AMENDED COUNTERCLAIMS OF DEFENDANT, SYNERX PHARMA, LLC** to be served by ECF and electronic mail on January 19, 2011, upon:

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Dated: January 19, 2011